Health Advisory:

Clostridium sordellii Toxic Shock Syndrome After Medical Abortion

July 26, 2005

This document will be updated as new information becomes available. The current version can always be viewed at http://www.dhss.mo.gov

The Missouri Department of Health & Senior Services (DHSS) is now using 4 types of documents to provide important information to medical and public health professionals, and to other interested persons:

Health Alerts convey information of the highest level of importance which warrants immediate action or attention from Missouri health providers, emergency responders, public health agencies, and/or the public.

Health Advisories provide important information for a specific incident or situation, including that impacting neighboring states; may not require immediate action.

Health Guidances contain comprehensive information pertaining to a particular disease or condition, and include recommendations, guidelines, etc. endorsed by DHSS.

Health Updates provide new or updated information on an incident or situation; can also provide information to update a previously sent Health Alert, Health Advisory, or Health Guidance; unlikely to require immediate action.

Office of the Director
912 Wildwood
P.O. Box 570
Jefferson City, MO 65102
Telephone: (800) 392-0272
Fax: (573) 751-6041
Web site: http://www.dhss.mo.gov

Health Advisory
July 26, 2005

FROM: **JULIA M. ECKSTEIN**
DIRECTOR

SUBJECT: ***Clostridium sordellii* Toxic Shock Syndrome After Medical Abortion with Mifepristone and Intravaginal Misoprostol**

CDC. *Clostridium sordellii* Toxic Shock Syndrome After Medical Abortion with Mifepristone and Intravaginal Misoprostol – United States and Canada, 2001-2005. *MMWR* 2005; 54(Dispatch):1.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm54d722a1.htm

On July 19, 2005, the Food and Drug Administration (FDA) issued a public health advisory regarding the deaths of four women in the United States after medical abortions with Mifeprex® (mifepristone, formerly RU-486; Danco Laboratories, New York, New York) and intravaginal misoprostol (*1*). [Excerpts from the advisory are provided below. The complete advisory is available at: http://www.fda.gov/cder/drug/advisory/mifeprex.htm]. Two of these deaths occurred in 2003, one in 2004, and one in 2005. Two of these U.S. cases had clinical illness consistent with toxic shock and had evidence of endometrial infection with *Clostridium sordellii*, a gram-positive, toxin-forming anaerobic bacteria. In addition, a fatal case of *C. sordellii* toxic shock syndrome after medical abortion with mifepristone and misoprostol was reported in 2001, in Canada (*2*). All three cases of *C. sordellii* infection were notable for lack of fever, and all had refractory hypotension, multiple effusions, hemoconcentration, and a profound leukocytosis. *C. sordellii* previously has been described as a cause of pregnancy-associated toxic shock syndrome (*3*).

Investigation by FDA, CDC, and state and local health departments into the two most recently identified U.S. deaths after medical abortion is ongoing. Empiric therapy for patients suspected of having postpartum or postabortion toxic shock syndrome should include antimicrobials with anaerobic activity against *Clostridium* species. Health-care providers are encouraged to report any cases of postpartum or postabortion toxic shock syndrome to their state [in Missouri, **800-392-0272**] or local health department and to CDC at telephone 800-893-0485. Cases potentially associated with use of mifepristone or misoprostol should also be reported through the FDA MedWatch system available at http://www.fda.gov/medwatch/index.html or telephone 800-FDA-1088.

References

1. Food and Drug Administration. *FDA Public Health Advisory: sepsis and medical abortion.* Rockville, Maryland: Food and Drug Administration, Center for Drug Evaluation and Research; 2005. Available at http://www.fda.gov/cder/drug/advisory/mifeprex.htm.
2. Sinave C, Le Templier G, Blouin D, Leveille F, Deland E. Toxic shock syndrome due to *Clostridium sordellii*: a dramatic postpartum and postabortion disease. *Clin Infect Dis* 2002;35:1441--3.
3. McGregor JA, Soper DE, Lovell G, Todd JK. Maternal deaths associated with *Clostridium sordellii* infection. *Am J Obstet Gynecol* 1989;161:987--95.

The FDA public health advisory (*FDA Public Health Advisory: Sepsis and Medical Abortion*) mentioned above contains the following recommendations:

- All providers of medical abortion and emergency room health care providers should investigate the possibility of sepsis in patients who are undergoing medical abortion and present with nausea, vomiting, or diarrhea and weakness with or without abdominal pain, and without fever or other signs of infection more than 24 hours after taking misoprostol. To help identify those patients with hidden infection, strong consideration should be given to obtaining a complete blood count.

- FDA recommends that physicians who suspect infection in patients with this presentation should consider immediately initiating treatment with antibiotics that includes coverage of anaerobic bacteria such as *Clostridium sordellii*.

- At this time FDA does not have sufficient information to recommend the use of prophylactic antibiotics.

The advisory also states that FDA is working with the manufacturers of Mifeprex and misoprostol tablets to conduct special tests to ensure that there was no contamination of either product with *Clostridium sordellii*.

If you have questions, please contact the Missouri Department of Health and Senior Services' Disease Investigation Unit at 573-751-6113, or 800-392-0272.